

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
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PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

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|--|---|
| Date of mailing (day/month/year) 08 JUN 2006 | |
| Applicant's or agent's file reference 414/04517 | FOR FURTHER ACTION See paragraph 2 below |
| International application No. PCT/IL05/00906 | International filing date (day/month/year) 18 August 2005 (18.08.2005) |
| Priority date (day/month/year) 25 August 2004 (25.08.2004) | |
| International Patent Classification (IPC) or both national classification and IPC IPC: A61H 1/00 (2006.01) A61B 5/04 (2006.01) USPC: 601/5,33;600/545 | |
| Applicant REABILITY INC. | |

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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| Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201 | Date of completion of this opinion 11 April 2006 (11.04.2006) | Authorized officer <i>For</i> Gregory L Huson Virginia Labeyrie Telephone No. (571) 272-3700 |
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/IL05/00906

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|---|-----|
| Novelty (N) | Claims <u>Please See Continuation Sheet</u> | YES |
| | Claims <u>Please See Continuation Sheet</u> | NO |
| Inventive step (IS) | Claims <u>Please See Continuation Sheet</u> | YES |
| | Claims <u>Please See Continuation Sheet</u> | NO |
| Industrial applicability (IA) | Claims <u>Please See Continuation Sheet</u> | YES |
| | Claims <u>Please See Continuation Sheet</u> | NO |

2. Citations and explanations:

Please See Continuation Sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 11,13,19 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claims are indefinite for the following reason(s): They recite the phrase "said measurement," indicating that a measurement was claimed earlier. However these claims, as well as their parent claim 1 do not claim a measurement. Therefore there is a lack of antecedent basis for the "said measurement."

Claim 60 is objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because the claim is indefinite for the following reason(s): It is not clear what is being claimed. It seems as part (a) and part (b) are identical for they both claim the reorganization of brain functions. Furthermore, part (b) is unclear and seems to be a run on sentence. Was a comma intended to be placed between "reorganizing" and "rehabilitating?"

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International application No.
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Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

V.1. Reasoned Statements:

The opinion as to Novelty was positive (Yes) with respect to claims 4,6,10-16,22,23,25,27,31,32,35-42,44,46-66,68,69,71-81

The opinion as to Novelty was negative (No) with respect to claims 1-3,5,7-9,17-21,24,26,28-30,33,34,43,45,67,70

The opinion as to Inventive Step was positive (Yes) with respect to claims 4,6,10-16,22,23,25,27,31,32,35-42,44,46-66,68,69,71-81

The opinion as to Inventive Step was negative (NO) with respect to claims 1-3,5,7-9,17-21,24,26,28-30,33,34,43,45,67,70

The opinion as to Industrial Applicability was positive (YES) with respect to claims 1-81

The opinion as to Industrial Applicability was negative (NO) with respect to claims NONE

V. 2. Citations and Explanations:

Claims 1-3,5,7-9,17-21,24,26,28-30,33,34,43,45,67,70, lack novelty under PCT Article 33(2) as being anticipated by Dean, Jr. et al.

Regarding claim 1, the reference comprises a movement element capable of controlling at least one motion parameter of a portion of a patient. The reference also suggests the monitoring of brain wave activity. A data acquisition computer encompasses circuitry and includes a memory for the storage of rehabilitation information. Because the reference states that the computer "responds appropriately to the patient's state of mind," it is evident that the signal for the brain wave monitor is interrelated with the movement of the movement element as part of a rehabilitation process.

Regarding claim 2, fig. 5 shows that a limb is put into motion.

Regarding claim 3, the data acquisition computer or circuitry controls the movement element.

Regarding claim 5, force is applied the portion of a patient against his/her movement. This constitutes resistance to movement.

Regarding claim 7, the said force is adjustable from zero to greater than the user's body weight. Thus the said circuitry must measure the force before it allows its adjustment, as well as after the said adjustment.

Regarding claim 8, pre-programmed or custom exercise regimens are provided and constitute a rehabilitation plan.

Regarding claim 9, feedback to the patient's performance is provided.

Regarding claims 17,18, because the invention of the reference comprises a brain wave monitor, it is capable of sending information to the circuitry that will detect an intent, as well as a readiness to move. Based on this "state of mind" the movement element "responds appropriately."

Regarding claim 19, in response to the user's production of insufficient force (a detection of movement or lack thereof) the apparatus will decrease the force.

Regarding claim 20, the recordings of readings from electrodes placed on a user's head are known as an electroencephalogram (EEG) and represent brain waves. Thus, a brain wave monitor encompasses an EEG monitor.

Regarding claim 21, the apparatus comprises a heart rate monitor, a device that inherently measure blood flow.

Regarding claim 24, the apparatus comprises means to provide force against the movement of a portion or a patient and is controllable by the circuitry.

Regarding claim 26, a body portion can either be engaged, or disengaged from the apparatus.

Regarding claim 28, the circuitry comprises a memory that stores a patient's performance data/rehabilitation progress.

Regarding claim 29, the apparatus comprises two movement elements that the circuitry moves in opposite directions to simulate walking, thus recognizing each as being associated with opposite limbs.

Regarding claim 30,33 see rejection of claim 1.

Regarding claim 34, the movement of the movement element comprises a plurality of motions.

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Regarding claim 43,45 a user's motion is measured and recorded as part of a patient's performance data.

Regarding claim 67,70, brain activity is measured during the repeated movements of the movement element and analyzed by the circuitry.

Claims 4,6,10-16,22,23,25,27,31,32,35-42,44,46-81 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the control of the direction and location of movement or a reach point by circuitry, the measurement of a parameter of motion of said movement element, a template of expected brain-motion relationship, the generation of expected motion based on the measurement of brain waves, the generation of expected brain activity based on movement, the comparison of said measurement to rehabilitation information as well as its trends, the change of a motion parameter responsive to said measurement within a time from of said movement, a fMRI brain wave monitor, a robotic manipulator, unrestricted movement in 3D space over 30cm volume, cognitive rehabilitation, brain rehabilitation, cortical reorganization, indications of brain plasticity, measuring and controlling said motion at least 10 times, repeating and controlling 20 different motions, comparing motions and measurements for a healthy side and a paretic side, measuring the quality of said motion, training the control of cortical activity, locally activating a brain region while applying treatment and delivering a drug, using external stimulation, detecting intent to carry out physical activity, a spatial manipulator, and measuring movement of a patient in response to imagery

Claims 1-81 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

If a demand for international preliminary examination is made, the written opinion of the International Searching Authority will, except in certain cases where the International Preliminary Examining Authority did not act as International Searching Authority and where it has notified the International Bureau under Rule 66.1*bis*(b), be considered to be a written opinion of the International Preliminary Examining Authority. If a demand is made, the applicant may submit to the International Preliminary Examining Authority a reply to the written opinion together, where appropriate, with amendments before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later (Rule 43*bis*.1(c)).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.